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Attorney Docket No. 2004367-0031

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Winterbottom, *et al.* Examiner: To be assigned

Serial No.: 10/735,135 Art Unit: 1644

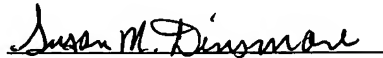
Filing Date: December 12, 2003

Title: FORMABLE AND SETTABLE POLYMER BONE COMPOSITE  
AND METHOD OF PRODUCTION THEREOF

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450  
Sir:

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on September 2, 2004.

  
Susan M. Dinsmore

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants request consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

(Select A, B, C or D below)

A. ☒ This Information Disclosure Statement has been filed:

1. ☐ within three months of the filing date of the above identified U.S. Patent application other than a continued prosecution application under § 1.53(d);
2. ☐ within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International application;

3. ☒ before the mailing date of the first Office Action on the merits in the above-identified application; or

4. ☐ before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

No fee or certification is required.

B. ☐ This Information Disclosure Statement has been filed more than three months after the filing date of the present application and after the mailing date of the first Office Action, but before the mailing date of any of a final action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application, and:

(check 1 or 2 below)

1. ☐ Please charge the \$180 fee under 37 C.F.R. §1.17(p) to our deposit account 03-1721, OR

2. ☐ The Applicants hereby certify, as specified in 37 C.F.R. §1.97(e), that  
(check a or b below)

a. ☐ each item of information contained in this (Supplemental) Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of the (Supplemental) Information Disclosure Statement; or

b. ☐ no item of information contained in this (Supplemental) Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the (Supplemental) Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement.

C. ☐ This Information Disclosure Statement has been filed after the mailing date of either a Final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311 and on or before payment of the Issue Fee.

1. The Applicants hereby certify, as specified in 37 C.F.R. §1.97(e), that:

a. ☐ each item of information contained in this (Supplemental) Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of the (Supplemental) Information Disclosure Statement; or

b. ☐ no item of information contained in this (Supplemental) Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the (Supplemental) Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement; AND

2. The Petition Fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed.

D. ☐ This Information Disclosure Statement does not comply with any of the provisions set forth above, or is being submitted after the payment of the issue fee; however, Applicants respectfully request that the Statement be placed in the above-referenced file.

PART II - 37 CFR § 1.98 Content of Information Disclosure Statement:

(Select A and B, and optionally C and/or D)

☒ A. Applicant hereby makes of record in the above-identified application all patents, publications, applications or other information submitted for consideration by the Office listed on the attached form PTO-1449 (modified). The order of presentation of the patents, publications, applications or other information should not be construed as an indication of the importance. Applicants have provided a legible copy of:

each U.S. patent application publication;

each U.S. foreign patent;

each publication or that portion which caused it to be listed;  
each pending U.S. application (including the application specification including the claims and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion); and  
other information or that portion which caused it to be listed.

Alternatively, if a written English-language translation of a non-English-language document, or portion thereof, if within the possession, or control of, or is readily available to any individual designated in §1.56(c), a copy of the translation is provided herein as identified:

[ ] B. The Applicants hereby make the following additional information of record in the above-identified application:

[ ] C. Applicant has not provided copies of those references indicated by an asterick because, in accordance with 37 CFR §1.98(d) each of them was previously cited in USSN \_\_\_\_\_, which is identified herein and is relied upon for an earlier effective filing date under 35 USC §120.

#### PART IV: Remarks

A copy of each of the above-identified U.S. and foreign patent(s), publication(s), application(s) or other information submitted is enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s), publication(s), application(s), or other information be printed on any patent which issues from this application.


By submitting this Information Disclosure Statement, Applicants make no representation that a search has been performed, of the extent of any search performed, or that more material information may not exist.

By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited materials. An early and favorable action is hereby requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Valarie B. Rosen", written over a horizontal line.

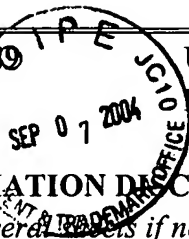
Valarie B. Rosen, Ph.D.

Registration. No. 45,698

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Boston, MA 02109  
(617) 248-5000  
Date: September 2, 2004

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Form PTO-1449  
(Modified)



U.S. Department of Commerce  
Patent and Trademark Office

Atty. Docket:  
2004367-0031

In re Application No.  
10/735,135

**INFORMATION DISCLOSURE STATEMENT**

(Use several sheets if necessary)

Applicant: Winterbottom, et al.

Filing Date:  
December 12, 2003

Group:

**U.S. PATENT DOCUMENTS**

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	3,892,649	Phillips, et al.	July 1, 1975	204	181
	3,949,073	Daniels, et al.	April 6, 1976	424	177
	4,183,874	Fan, et al.	January 15, 1980	525	100
	4,551,156	Li	November 5, 1985	55	16
	4,645,503	Lin, et al.	February 24, 1987	623	16
	4,783,504	St. Clair, et al.	November 8, 1988	525	72
	5,162,445	Powers, et al.	November 10, 1992	525	333.4
	5,246,782	Kennedy, et al.	September 21, 1993	428	421
	5,262,461	Serizawa, et al.	November 16, 1993	524	262
	5,324,519	Dunn, et al.	June 28, 1994	424	426
	5,333,626	Morse, et al.	August 2, 1994	128	898
	5,468,544	Marcolongo, et al.	November 21, 1995	428	224
	5,513,662	Morse, et al.	May 7, 1996	128	898
	5,606,000	Jadhav, et al.	February 25, 1997	528	29
	5,626,861	Laurencin, et al.	May 6, 1997	424	426
	5,736,372	Vacanti, et al.	April 7, 1998	435	180
	5,766,618	Laurencin, et al.	June 16, 1998	424	426
	5,846,484	Scarborough, et al.	December 8, 1998	422	28
	5,948,386	Katti, et al.	September 7, 1999	424	1.77
	6,027,744	Vacanti, et al.	February 22, 2000	424	426
	6,165,486	Marra, et al.	December 26, 2000	424	423
	6,352,667	English, James P.	March 5, 2002	264	328.17
	6,399,693	Brennan, et al.	June 4, 2002	524	494
	6,406,498	Törmälä, et al.	June 18, 2002	623	23.75
	6,432,436	Gertzman, et al.	August 13, 2002	424	423

<b>Form PTO-1449</b> <b>(Modified)</b>		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 2004367-0031		In re Application No. 10/735,135	
<b>INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)				Applicant: Winterbottom, et al.			
				Filing Date: December 12, 2003		Group:	
<b>U.S. PATENT APPLICATIONS</b>							
Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:		
	US2002/0098222	Wironen, et al.	July 25, 2002	424	423		
	10/639,912	Shimp, et al.	August 12, 2003		1615		
	10/681,651	Shimp, et al.	October 8, 2003		1615		
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner's Initials	Document No.	Country	Date	Translation			
				Yes	No		
	WO 98/19718	PCT	14 May 1998				
<b>OTHER DOCUMENTS</b>							
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)						
	International Search Report for PCT/US03/25417.						
	International Search Report for PCT/US03/39704.						
	Baker, Gregory L., <a href="http://www.cem.msu.edu/~gradoff/brochf/Baker.htm">http://www.cem.msu.edu/~gradoff/brochf/Baker.htm</a> , printed August, 2002.						
	Boesch, P., "Bone Grafting with Fibrin Glue", <i>Wiener Klinische Wochenschrift Supplementum</i> , 93, No. 124, pp. 3-26, 1981.						
	Han, et al., "Synergistic Effects of Lecithin and Human DBM on Bone Induction in Nude Rats", <i>Society for Biomaterials</i> , 28 <sup>th</sup> Annual Meeting Transactions, 2002 (abstract).						
	Hooper, et al., "Diphenolic Monomers Derived from the Natural Amino Acid $\alpha$ -L-Tyrosine: An Evaluation of Peptide Coupling Techniques", <i>Journal of Bioactive and Compatible Polymers</i> 10, 327-340 (1995).						
	Nazhat, S.N., et al., "Dynamic Mechanical Behaviour of Modified Hydroxyapatite Reinforced Polyethylene Composites", <i>Fifth World Biomaterials Congress</i> , p. 83, May 29-June 2 (1996)						
	Satish Pulapura, et al., "Tyrosine-Derived Polycarbonates: Backbone-Modified "Pseudo"-Poly (Amino Acids) Designed for Biomedical Applications", <i>Biopolymers</i> 32, 411-417 (1992)						
	"Silane Coupling Agent", <a href="http://www.apr.co.kr/silaneen.htm">http://www.apr.co.kr/silaneen.htm</a> , printed August 7, 2002.						
	Simmons, D.M., et al., "Evaluation of collagen cross-linking techniques for the stabilization of tissue matrices", <i>Biotechnol. Appl. Biochem.</i> 17, 23-29 (1993) (abstract only).						
	Tangpasuthadol, Varawut, "Thermo-Mechanical Properties and Hydrolytic Degradation of Tyrosine-Derived Polymers for Use in Biomedical Applications", Ph.D. Dissertation, Rutgers,						

<b>Form PTO-1449</b> <b>(Modified)</b>		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 2004367-0031	In re Application No. 10/735,135
<b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>				Applicant: Winterbottom, et al.	
				Filing Date: December 12, 2003	
				Group:	
	The State University of New Jersey, (January, 1999).				
	Whittaker, et al., "Matrix Metalloproteinases and their Inhibitors – Current Status and Future Challenges", <i>Celltransmissions</i> , <b>17</b> , prior to June 13, 2002.				
	Zhiyuan Zhong, et al., "Calcium methoxide initiated ring-opening polymerization of ε-caprolactone and L-lactide", <i>Polymer Bulletin</i> <b>46</b> , 51-57 (2001).				
EXAMINER			DATE CONSIDERED		
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					